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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,150	09/30/1999	WALTHERUS JACOBUS W VAN VENROOIJ	30394-1027	5796

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/06/2004

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,150

Applicant(s)

VAN VENROOIJ ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,15-18,21,23-26 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,15-18,21,23-26 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/NL97/00624.

Claims 2, 3, 10-14, 19, 20, 22 and 27 have been canceled. It is noted that claims 10-14 are noted as "Withdrawn" on the amendment filed July 25, 2003. However, claims 10-14 were canceled in Applicant's amendment filed July 6, 2001.

Claims 16-35 have been added.

Accordingly, claims 1, 4-9, 15-18, 21, 23-26 and 28-35 are currently pending and the subject of examination in the present Office Action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2003 (copy refiled December 12, 2003) has been entered. This Office Action is made NON-FINAL.

Chronology note:

On July 25, 2003 Applicant timely filed a request for an extension of time and a response under 37 CFR § 1.116 to the Final Office Action mailed March 25, 2003. Due to processing by the Office of a petition filed by Applicant, the amendment was not forwarded to the Examiner for action. In addition the filed paper was not matched with the application. In the interest of not allowing pendency of the application to lapse, Applicant filed a request for continued examination (RCE) and another request for an extension of time on August 25, 2003, which was still prior to action on the amendment. At the request of the Examiner, Applicant resubmitted on December 10, 2003, by facsimile, a copy of the response filed July 25, as well as a PTO-stamped postcard receipt for said paper. After the file was forwarded to the Examiner, the Examiner telephoned Applicant's representative Slusher on December 19, 2003 to inform him that the Examiner would be issuing an Advisory Action indicating non-entry of the amendment filed July 25, 2003 due to additional consideration, followed by the issuance of a new Non-Final Office Action responsive to the RCE requesting entry of the previously submitted paper. The instant paper is the Non-Final Office Action.

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The following represents a prior ground of rejection that has been MAINTAINED.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5, 7-9, 15-18, 25, 26, 28, 30, 31 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "Written Description" rejection.

Applicant's arguments filed July 25, 2003 have been fully considered but they are not persuasive. Applicant traverses the rejection on the grounds that the claims are specifically amended to be specific for citrulline and that because the Examiner "notes that the disclosed peptides of SEQ ID NOs: 1-10 are derived from two areas of one protein which contains one type of arginine modification (citruline)" that the amended claims as now amended are enabled as stated by the Examiner and therefore meet the written description requirement.

The Examiner respectfully disagrees with Applicant's analysis. At the outset, Applicant is reminded that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111). The central issue is not that the Examiner recognized that there were 10 different peptides described in the specification, but that all 9 of the linear peptides and the single cyclic peptide are obtained from the same human protein. In other words, the description is limited to peptides from a single protein and cannot be considered to be descriptive of fillagrin or profillagrin proteins obtained from other species. In fact, Applicant has reported that it is recognized in the art that the description of one fillagrin or profillagrin protein does not extend to a description of others. In the sentence bridging pages 12 and 13 of the response filed July 25, 2003 Applicant states:

"It is noted that it was known in the art at that time that the sequences of profillagrin and fillagrin differ greatly even within a single individual. See, e.g., Gan et al., *Biochemistry* 29:9432-9440 (1990).

Accordingly, the written description of SEQ ID NOs: 1-9 and the cyclic peptide of SEQ ID NO: 10 in the present specification cannot be held as an adequate written description of other filaggrin or

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profilaggrin peptides, as it would not be recognized by one of skill in the art that Applicant was in possession of filaggrin or profilaggrin peptides other than SEQ ID NOs: 1-9 and the cyclic peptide of SEQ ID NO: 10, as the sequences of SEQ ID NOs: 1-9 and the cyclic peptide of SEQ ID NO: 10 are not predictive of other filaggrin or profilaggrin peptide sequences.

The following represents a NEW ground of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7-9, 15-18, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al (J. Clin. Invest. 92:11387-1393, 1993; of record) as evidenced by Tarsca et al (J. Biol. Chem. 271(48):30709-30716, 11/1996; U1 on form PTO-892).

Simon teaches human filaggrin protein purified from epidermis (Abstract and page 1388, first column in particular). Simon teaches that purified filaggrin is specifically recognized by autoantibodies in the sera of RA patients to a 40K protein extracted from epidermis identified to be a neutral/acidic form of filaggrin and the purification of the 40K form of filaggrin (Abstract in particular). It is noted that the modification of arginine was not taught by Simon and that Simon was not clear on the origin of the neutral/acidic 40K form of filaggrin (page 1391, second new paragraph of second column in particular). However, the claimed functional limitations would be inherent properties of the referenced peptides, as evidenced by Tarsca. Tarsca discloses that filaggrin is a natural substrate of peptidylarginine deiminase, an enzyme commonly found in mammalian cells that catalyzes the conversion of arginine residues to citrulline residues (see entire publication, Abstract in particular). It is known that deimination of the arginine residues will render the filaggrin protein less basic (page 30709, second new paragraph of second column in particular). The teachings of Tarsca further evidence that the conversion of arginine residues to citrulline in filaggrin is a post-translational modification. The prior art teaching anticipates the claimed invention. Claim 7 is included because there is no physical difference between a natural peptide and its synthetic copy.

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Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 5, 2004

Pat. J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

2/5/04